

**VERSION WITH MARKINGS SHOWING CHANGES MADE TO CLAIMS**

**In the Claims**

Kindly cancel claims 3-5.

Kindly amend claims 1-2 and 6-10 as follows.

1. (Amended) A metering valve for dispensing a pharmaceutical product, comprising: [notably]  
a valve body [(1)], [and]  
a metering chamber [(2)] constructed from a fluorinated polymer, and  
a valve stem [(10) sliding in said metering chamber (2) between a position of rest and a position of actuation, characterized in that at least one part of said metering valve is made of a material adapted to reduce the deposition, adhesion and/or coating of product on the valve].
2. (Amended) [A] The metering valve according to claim 1, [in which said metering chamber (2) is made of a material adapted to reduce the deposition, adhesion and/or coating of product on said metering chamber] wherein the fluorinated polymer is a fluorinated ethylene propylene, a polytetrafluoroethylene, a copolymer of a polytetrafluoroethylene, or combinations thereof
6. (Amended) [A] The metering valve according to claim 1, [in which said material adapted to reduce the deposition, adhesion and/or coating of product contains a] wherein the fluorinated polymer is polytetrafluoroethylene.
7. (Amended) [A] The metering valve according to claim [6] 1, [in which said material consists] wherein the metering chamber is made essentially from [essentially of] a fluorinated polymer.

8. (Amended) [A] The metering valve according to claim [6] 7, [in which said material contains] wherein the metering chamber is made essentially from polytetrafluoroethylene.
9. (Amended) [A] The metering valve according to claim 8, [in which said material consists essentially of polytetrafluoroethylene (PTFE)] wherein the metering chamber is made essentially from a fluorinated ethylene propylene, a polytetrafluoroethylene, a copolymer of a polytetrafluoroethylene, or combinations thereof.
10. (Amended) A metered dose inhaler [device for dispensing of a fluid product] comprising:
  - an aerosol container containing [the product] a drug and a hydrofluoroalkane propellant, [gas, and a metering valve made according to claim 1, mounted in the said container for selective dispensing of said product, in which the propellant gas is an HFA gas]
  - a valve body,
  - a metering chamber constructed from a fluorinated polymer, and
  - a valve stem.

REMARKS

Claims 1, 2 and 6-10 are pending. Claims 1, 2 and 6-10 stand rejected. The claims have been amended to more particularly point out and distinctly claim the subject matter Applicant regards as the invention. Support for the claimed invention is found in the application as originally filed. No new matter has been added.

At ¶¶'s 2-3 of the Office Action, claims 1, 2 and 6-10 stand rejected under 35 USC 112, Second Paragraph, as being indefinite. The claims have been amended to more clearly particularly point out and distinctly claim the subject matter Applicant regards as the invention. Reconsideration and withdrawal of the rejections is respectfully requested.

At ¶¶'s 4-5 of the Office Action, claims 1, 6, 8 and 10 stand rejected under 35 USC 102(b) as being anticipated by WO 97/16360. For convenience, the Examiner and Applicant refers to USPN 6,112,950 (the '950 patent) which is based on WO 97/16360.

The '950 patent discloses an metered dose inhaler having, among other components, a metering chamber 2 and a valve plunger 10. The plunger 10 corresponds to the valve stem of the present invention. The valve plunger includes a top element 10a and a bottom element 10b. (See col. 3, lines 3-23 and Figs. 1 and 2). The valve plunger 10 is molded from a mixture of acetal resin, PTFE and silicone to lower friction with the valve gasket. (See col. 2, lines 22-38). The '950 patent does not suggest or teach making any components (other than the plunger) using a fluorinated polymer, such as PTFE. The '950 patent is also silent regarding drug deposition on any components of the MDI, such as the metering chamber.

The instantly claimed invention is patentably novel and nonobvious over the '950 patent because, *inter alia*, the reference does not disclose a metering chamber made from a fluorinated polymer. Reconsideration and withdrawal of the rejections is respectfully requested.

At ¶¶'s 6 of the Office Action, claims 1 and 2 stand rejected under 35 USC 102(b) as being anticipated by USPN 5,169,038 (the '038 patent). The '038 patent discloses a metering valve having a valve body 1 (which defines the

metering chamber 7) "conventionally molded in thermoplastic material." (Col. 3, lines 67-68). The instantly claimed invention is patentably novel and nonobvious over the '038 patent because, *inter alia*, the reference fails to disclose a metering chamber made from a fluorinated polymer.

Reconsideration and withdrawal of the rejections is respectfully requested.

At ¶¶'s 8-9 of the Office Action, claims 6-9 stand rejected under 35 USC 103(a) as being obvious over the '038 patent and USPN 5,147,075 (the '075 patent). The '075 patent discloses a pressurized container having a valve assembly 6 and a frame 21 made from a corrosion resistant material, such as Teflon. (Col. 3, lines 35-42). The frame 21 is fixed to a threaded member 12. The frame and threaded member connect the actuating mechanism 1 to the container 10.

Applicant respectfully traverses the rejection because, *inter alia*, the references fails to teach or suggest a metering chamber made from a fluorinated polymer. Although the '075 patent discloses a component part made from Teflon, that part (i.e., frame 21) does not correspond to the instantly claimed metering chamber. Instead, the frame 21 is more akin to a conventional ferrule in metered dose inhalers. One of ordinary skill in the art would not reasonably recognize the teaching of a Teflon ferrule used to prevent corrosion as having any relevance to or interchangeability with a metering chamber made from a fluorinated polymer to reduce/prevent drug deposition. Thus, the '075 and '038 patents fail to establish a *prima facie* case of obviousness for the reasons set forth herein.

Reconsideration with withdrawal of the obviousness rejections is respectfully requested.

For the above reasons, Applicants respectfully traverse the rejections and objections set forth in the outstanding Office Action and request that they be withdrawn. Applicants respectfully contend that the application is in condition for allowance and requests the same. The Examiner is invited to contact the undersigned should there be any questions or concerns.

Respectfully submitted,

  
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